10/540843
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AMENDMENTS TO THE CLAIMS

1.-7. **Canceled**

8. **(Currently amended)** A pharmaceutical composition for the delivery of a therapeutic agent comprising:

(A) a therapeutic agent; and

(B) an effective amount of rotavirus protein VP4, or its derived polypeptide VP8, its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them as well as their mixtures~~,~~

~~(C) optionally an acceptable pharmaceutical vehicle~~.

9. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is an oral dosage composition for intestinal delivery of ~~a~~ the therapeutic agent, and administering is by oral administration.

10. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is a nasal dosage composition for administering by nasal administration.

11. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is a cutaneous dosage composition for administering by the skin.

12. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is a vaginal dosage composition for administering by the vagina.

13. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is a rectal dosage composition for administering by the rectum.

14. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is in the form of an aerosol dosage composition for administering to the respiratory system.

15. **(Currently amended)** ~~A~~ The pharmaceutical composition as claimed in claim 8, wherein said composition is an intravenous dosage composition for delivery of said therapeutic agent through the blood-brain barrier, and said administering is by intravenous administration.

16. **(Currently amended)** The pharmaceutical composition ~~therapeutic agent employed~~ as claimed in claim 8, wherein said therapeutic agent is a ~~can be any~~ drug, a peptide

with biological activity, a vaccine, or any composition that is not adequately absorbed by the transcellular route~~, without taking into account its size or charge~~.

17. **(Currently amended)** The ~~drugs employed~~ pharmaceutical composition as claimed in claim 16, wherein said drug is selected from ~~are~~ those that act on the cardiovascular system, the central nervous system, antineoplastic drugs and ~~to~~ antibiotics.

18. **(Original)** The pharmaceutical composition of claim 17, wherein said drug which acts on the cardiovascular system is selected from the group consisting of lidocaine, adenosine, dobutamine, dopamine, epinephrine, norepinephrine and phentolamine.

19. **(Original)** The pharmaceutical composition of claim 17 wherein said drug which acts on the central nervous system is selected from the group consisting of doxapram, alfentanil, dezocin, nalbuphine, buprenorphine, naloxone, ketorolac, midazolam, propofol, metacurine, mivacurium and succinylcholine.

20. **(Original)** The pharmaceutical composition of claim 17, wherein said antineoplastic drug is selected from the group consisting of cytarabine, mitomycin, doxorubicin, vincristine and vinblastine.

21. **(Original)** The pharmaceutical composition of claim 17, wherein said antibiotic is selected from the group consisting of methicillin, meziocillin, piperacillin, cetoxitin, cefonicid, cefmetazole and aztreonam.

22. **(Original)** The pharmaceutical composition of claim 16, wherein said biologically active peptide is selected from the group consisting of a hormone, lymphokine, globulin and albumin.

23. **(Original)** The pharmaceutical composition of claim 22, wherein said hormone is selected from the group consisting of testosterone, nandrolene, menotropins, insulin and urofolltropin.

24. **(Original)** The pharmaceutical composition of claim 22, wherein said lymphokine is selected from the group consisting of interferon-alpha, interferon-beta, interferon-gamma, interleukin-1, interleukin-2, interleukin-4 and interleukin-8.

25. **(Original)** The pharmaceutical composition of claim 22, wherein said globulin is selected from the group consisting of alpha-globulins, beta-globulins and immunoglobulins.

26. **(Original)** The pharmaceutical composition of claim 22, wherein said globulin is an immunoglobulin selected from the group consisting of polyvalent IgG, and specific IgG, IgA or IgM.

27. **(Currently amended)** The pharmaceutical composition of claim 22, wherein said albumin ~~albumins~~ is selected from the group consisting of human ~~serie~~ serum albumin and ovalbumin.

28. **(Currently amended)** The pharmaceutical composition of claim 16, wherein said vaccine is selected from the group consisting of viral peptidic antigens, attenuated microorganisms, ~~as well as~~ and vaccines based in RNA replicons, small interfering RNAs (siRNAs), virus like particles (VLPs), subunit virus vaccines, DNA and RNA vaccines.

29. **(Currently amended)** The pharmaceutical composition of claim 28, wherein said peptidic ~~antigen~~ antigens include ~~the~~ B subunit of ~~the~~ heat sensitive enterotoxin of enterotoxic *E. coli*, ~~the~~ B subunit of cholera toxin, capsular antigens of enteric pathogens, fimbria and pili of enteric pathogens, surface antigens of HIV, dust allergens and acarus.

30. **(Currently amended)** The pharmaceutical composition of claim 28, wherein said attenuated microorganisms ~~include~~ comprise those of enterotoxic *E. coli*, enteropathogen *E. coli*, enterohemorragic *E. coli*, enteroinvasive *E. coli*, Vibrio Cholera, *Shigella flexneri*, *Salmonella typhy*, *Helicobacter pylori*, rotavirus, astrovirus, adenovirus and calicivirus.

31. **(Original)** The pharmaceutical composition of claim 8, wherein said the therapeutic agent is insulin.

32. **(Currently amended)** A method for treating diabetes comprising orally administering, to a diabetic subject, an oral dosage composition for intestinal delivery of a therapeutic agent comprising:

(A) a therapeutically effective amount of insulin; and

(B) an intestinal absorption enhancing effective amount of ~~of~~ rotavirus protein VP4, its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them ~~as well as~~ or their mixtures.

33. **(Currently amended)** A method for the treatment of cancer comprising ~~the~~ administering by any route, to a cancerous subject, rotavirus protein VP4, its functional variants,

derived proteins, derived fusion proteins and functional so peptides derived from them ~~as well as~~ or their mixtures, together with an acceptable pharmaceutical vehicle.

34. **(Currently amended)** A method for treating cancer in mammals, ~~where~~ wherein epithelial transformation is related to over expression of tight junction proteins, comprising ~~the~~ administering by any route, of rotavirus protein VP4, its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them ~~as well as~~ or their mixtures.

35. **(Currently amended)** A method ~~to treat~~ for treating cancer and/or inhibit metastasis, by disrupting the growth of new capillaries comprising ~~the~~ administering by any route, of rotavirus protein VP4, its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them ~~as well as~~ or their mixtures, thereby disrupting the growth of new capillaries.

36. **(Currently amended)** A method ~~to reduce~~ for reducing unwanted cellular adhesion that ~~can occur~~ occurs between tumor cells or normal cells, as a result of surgery, injury, chemotherapy, disease, inflammation or other pathological condition, comprising ~~the~~ administering by any route, of rotavirus protein VP4, its functional variants, derived proteins, derived fusion proteins and functional peptides derived from them ~~as well as~~ or their mixtures.

37. **(Currently amended)** A method for determining ~~the~~ regions or ~~the~~ derived peptides of proteins VP4, VP8, or of their functional variants and fusion proteins, that enhance or modulate ~~the~~ opening of ~~the~~ a paracellular pathway, comprising:

A) culturing ~~culture~~, extracting ~~extraction~~ or isolating ~~isolation of~~ an epithelia or endothelia;

B) ~~determination of the~~ determining a transepithelial electrical resistance (TER) of said epithelia or endothelia ~~such tissue~~;

C) ~~addition of~~ adding peptides, fragments, fusion proteins or functional derivatives of proteins VP4 and VP8 to said epithelia or endothelia; and

D) ~~optionally a molecule or compound unable to cross a sealed paracellular pathway could be added;~~

~~E) Identification of the~~ identifying proteins and peptides derived from proteins VP4 and VP8, or of their mixtures, that ~~have been~~ are able to diminish the TER of the

~~tissue~~ epithelia or endothelia ~~or that have allowed the passage of a paracellular tracer molecule~~.

38. **(Original)** An isolated peptide with SEQ. ID. NO. 3.

39. **(Original)** An isolated peptide with SEQ. ID. NO. 4.

40. **(Original)** An isolated peptide with SEQ. ID. NO. 5.

41. **(Original)** An isolated peptide with SEQ. ID. NO. 6.

42. **(Currently amended)** ~~A~~ An isolated peptide with SEQ. ID. NO. 7.

43. **(New)** The pharmaceutical composition of Claim 8 further comprising an acceptable pharmaceutical vehicle.

44. **(New)** The method of Claim 37, further comprising after step C):

adding a molecule or a compound unable to cross a sealed paracellular pathway, and

identifying proteins or peptides derived from proteins VP4 and VP8, or their mixtures that enabled passage of said molecule or compound across paracellular pathway.